

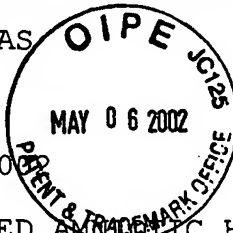


JC14 Rec'd PCT/PTO 06 MAY 2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : SPYROS TSAKAS
Serial No.: 10/089,486
Filed : March 27, 2002
For : CRYOPRESERVED AMNIOTIC HUMAN
CELLS FOR FUTURE THERAPEUTIC,
DIAGNOSTIC, GENETIC AND OTHER
USES



Docket No.: 02-314
Examiner :
Art Unit :

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900 Chapel Street
Suite 1201
New Haven, CT 06510-2802

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks
United States Patent & Trademark Office
Washington, D.C. 20231

Dear Sir:

In compliance with Applicant's duty of disclosure, the following documents are brought to the Examiner's attention:

"A Cryopreservative Procedure for Storing Cultivated and Uncultivated Amniotic Fluid Cells in Liquid Nitrogen", by S. Pentz et al., Journal of Medical Genetics, vol. 17, 1980, pp. 472-475;

"Transport and Storage of Amniotic Fluid Samples for Prenatal Diagnosis of Metabolic Diseases", by M.F. Niermeijer et al., Humangenetik, vol. 20, no. 2, 1973, pp. 175-178;

"Graft of Cryopreserved Human Amniotic Epithelial Cells in a Subject with Type B Niemann-Pick Disease", by B. Scaggiante et al., Pediatria Medica E. Chirurgia, vol. 9,



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no. 1, January, 1987 - ~~Technology~~, 1987, pp. 89-92;

PCT Patent Publication WO 97/35472 to Oliver et al.;

U.S. Patent No. 5,879,937 to Roncarolo;

EPC Patent Document 0 333 328 to Sackier et al.;

EPC Patent Document 0 815 867 to Sakuragawa;

"Therapeutic Cloning: Needs and Prospects", by A. Kind et al., Seminars in Cell & Development Biology, vol. 17, no. 3, June 1999, pp. 1171-1174; and

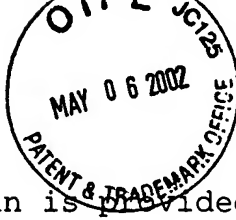
PCT Patent Publication WO 00/73421 to Hu et al.

The Pentz et al. article relates to the cryopreservation of cultured and uncultured amniotic fluid cells.

The Niermeijer et al. article relates to a method for freezing uncultured amniotic fluid cells to allow their use as a pregnancy-age matched controls in prenatal diagnosis of metabolic diseases.

The Scaggiante et al. article relates to the implantation of pure cryopreserved epithelial cells obtained by enzymatic digestion of human amnion.

The Oliver et al. patent document relates to methods and compositions for cryopreserving somatic cells. In one embodiment, a cell cryopreservation medium is provided which includes an effective amount of arabinogalactan to maintain the viability of cells upon freezing, storage and thawing. The cells may be cooled or frozen during storage to a temperature about or below 4°C, for example, to about -196°C. In one preferred embodiment, ultrarefined



arabinogalactan is provided in the cryopreservation medium, optionally in combination with a second cryopreservation agent, such as dimethyl sulfoxide. The medium can be used for the cryopreservation of a wide variety of different cell types from different sources. For example, mammalian cells, including porcine, canine, human, equine, rodent and bovine cells can be cryopreserved in the medium. The presence of arabinogalactan in the medium protects the viability of cells in the medium during the process of freezing, storage and thawing.

U.S. Patent No. 5,879,937 to Roncarolo relates to improved methods of prenatal diagnosis that can be performed either in pregnancy, and/or with greater safety, and/or rapidity, and/or with greater accuracy than conventional methods. A volume of amniotic fluid containing fetal cells is extracted from a pregnant woman, and the fetal T-cells are propagated in a culture medium comprising one or more cytokines. The fetal T-cells are then diagnosed for genetic defects.

The Sackier et al. patent document relates to the application of amniotic cells, in particular, viable epithelial cells, to clinical procedures including the treatment of diseased or damaged tissues, e.g. in joints denuded of cartilage and vascular grafts. The invention also provides prosthetic devices which incorporate amniotic cells, and compositions for cosmetic use based upon amniotic cells or cell extracts. A further development uses amniotic



cells in the form of a semipermeable membrane, or coated onto, for example, microspheres; these structures act as filtration devices for the removal of toxic materials from, for example, blood or urine.

The Sakuragawa patent document relates to cells used for treating dementia. The cells for treating dementia comprises human amniotic epithelial cells. By transplanting the cells for treating dementia into the brain, since the transplanted cells produce chlorine acetyltransferase, the dementia such as Alzheimer's disease is cured or lightened.

The Kind et al. article relates to reprogramming human somatic nuclei by transfer into oocytes.

The Hu patent document is directed to human amniotic epithelial cells derived from placenta at delivery, and the methods for isolating, culturing, and cryopreserving them for future therapeutic uses. Additionally, the invention is directed to methods for inducing differentiation of these multipotentials cells, for assaying the cell types derived, and for manipulating the cells by gene transfection and other means for therapeutic applications, including but not limited to enzyme replacement and gene therapy, tissue regeneration and replacement, as well as burn and wound dressings.

Copies of the above documents and a listing on Form PTO-1449 are enclosed herewith.

None of the patent documents are believed to negate the patentability of the present invention.

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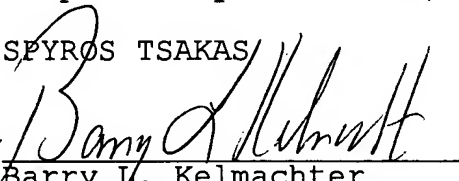


No fee is believed to be due as a result of this Information Disclosure Statement. Should the Commissioner determine that a fee is due, he is hereby authorized to charge said fee to Deposit Account No. 02-0184.

Respectfully submitted,

SPYROS TSAKAS

By


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Attorney for Applicant

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Date: April 23, 2002

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231

on April 23, 2002

(Date of Deposit)

Nicole Motzer

Name and Reg. No. of Attorney



Signature

April 23, 2002

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	2
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Complete If Known

Application Number	10/089,486
Filing Date	March 27, 2002
First Named Inventor	TSAKAS
Group Art Unit	
Examiner Name	
Attorney Docket Number	02-314

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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**Examiner
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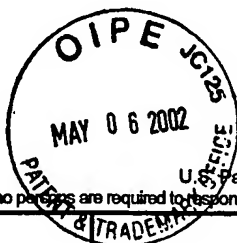
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known

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First Named Inventor	TSAKAS
Group Art Unit	
Examiner Name	
Attorney Docket Number	02-314

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	/	"A Cryopreservative Procedure for Storing Cultivated and Uncultivated Amniotic Fluid Cells in Liquid Nitrogen", by PENTZ ET AL., Journal of Medical Genetics, vol. 17, 1980, pp. 472-475	
	/	"Transport and Storage of Amniotic Fluid Samples for Prenatal Diagnosis of Metabolic Diseases", by NIERMEIJER ET AL., Humangenetik, vol. 20, no. 2, 1973, pp. 175-178	
	/	"Graft of Cryopreserved Human Amniotic Epithelial Cells in a Subject with Type B Niemann-Pick Disease", by SCAGGIANTE ET AL., Pediatria Medica E Chirurgia, vol. 9, no. 1, January 1987 - February 1987, pp. 89-92	
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